UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ROBERT AND KAROL AVENDT,

Plaintiffs, **CIVIL ACTION NO. 11-CV-15538**

VS. **DISTRICT JUDGE PAUL D. BORMAN**

COVIDIEN, INC., **MAGISTRATE JUDGE MONA K. MAJZOUB**

Defendant.
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ORDER ON DEFENDANT'S MOTION FOR CLARIFICATION AND FOR EXTENSION (DOCKET NO. 49)

This matter comes before the Court on Defendant's motion for clarification and for extension. (Docket no. 49). Plaintiffs filed a response. (Docket no. 66). Defendant filed a reply. (Docket no. 67). The motion has been referred to the undersigned for determination pursuant to 28 U.S.C. § 636(b)(1)(A). (Docket no. 52). The Court dispenses with oral argument on the motion pursuant to E.D. Mich. LR 7.1(f). This matter is now ready for ruling.

The parties appeared for a hearing on Plaintiffs' motion to compel discovery on July 24, 2013. (Docket no. 23). At the hearing, Plaintiffs agreed to narrow their discovery requests and Defendant agreed to supplement certain responses. (Docket no. 53). Following the hearing the Court entered a written order compelling Defendant to serve supplemental written responses and produce documents responsive to three discovery requests. Defendants now seek clarification of the Court's order with respect to Plaintiffs' First Interrogatory no. 16 and Second Request for Production no. 4.

Plaintiffs' First Set of Interrogatories no. 16 asks Defendant to state whether it has ever had

communications with the FDA regarding the use of Permacol, including but not limited to the use of Permacol for abdominal wall repairs, and if so, provide the name, address and telephone number of each person who participated in the communication, the date of the communication and a description of the communication. (Docket no. 23, ex. 1 at 10). Following a lengthy discussion during the motion hearing, Plaintiff agreed to narrow the request such that it seeks information pertaining to all written correspondences between Defendant and the FDA from 2003 to the present regarding the use of Permacol in hernia repairs as it relates to the (1) failure to test Permacol for use in hernia repair surgery prior to implantation, and (2) failure to conduct testing on the clinical effects of the cross-linking process used in the manufacturing of Permacol. (Docket no. 53 at 1579-81, 1585, 1590-92). The Court ordered Defendant to serve by August 19, 2013 a supplemental written response identifying information responsive to Plaintiffs' First Interrogatory no. 16 as that request was narrowed at the motion hearing. (Docket no. 40).

Defendant now moves to clarify the Court's order with respect to First Interrogatory no. 16. Defendant states that it interprets the "prior to implantation" language of the order to require it to produce correspondence pertaining to any "FDA correspondence relating to contentions that TSL[1] failed to properly test Permacol for abdominal wall hernias prior to seeking clearance in 1999." (Docket no. 49 at 7 and ex. B). Defendant argues that the "prior to implantation" language is subject to two interpretations, only one of which makes sense: (1) prior to implantation (use) in the United States pursuant to K992556, or (2) prior to implantation in Mr. Avendt. Defendant contends that the first interpretation is the only one that makes sense because there is no contention that specific testing would be required for the specific device used in Mr. Avendt's procedure. Defendant also

[1]Defendant states that TSL is its predecessor company, Tissue Science Laboratories.

seeks clarification that the order does not encompass 510(k) applications or indications-for-use not at issue in this case, such as Permaocol's use in the head, face, rotator cuff, and vaginal prolapse.

The Court will attempt to clarify it's order. First, request no. 16 is an interrogatory and not a production request. Therefore, the Court did not order Defendant to produce any documents responsive to that request. Instead, the Court ordered Defendant to serve a supplemental written response identifying information responsive to the request as it was narrowed at the hearing and agreed upon by the parties. Second, the hearing transcript makes it clear that the "prior to implantation" language of the narrowed request no. 16 pertains to the implantation of Permacol into Mr. Avendt. (Docket no. 53 at 1593-94). Thus, Plaintiffs seek information identifying any written correspondences dated 2003 through the present that were exchanged between Defendant and the FDA related to (1) the failure to test, prior to the date of Mr. Avendt's December 2008 ventral incisional hernia surgery, Permacol's application for use in abdominal wall hernia repairs, and (2) the failure to conduct testing on the clinical effects of the cross-linking process used in the manufacturing of Permacol. Request no. 16 is limited to testing conducted on the applications for use cleared in 510(k) K992556,[2] and more specifically, pertains only to the use of Permacol in abdominal wall hernia repairs and not for applications or indications for use not at issue in this case. The Court reiterates that the information Plaintiffs seek pertains to written correspondences dated from 2003 through the present.

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[2]The Court is of the understanding that Permacol was cleared in 510(k) K992556 for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Defendant's original 510(k) for Permacol (K992556) provides that Permacol is especially indicated for the repair of (1) abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical and incisional hernias; (2) colon, rectal, urethral and vaginal prolapse; (3) muscle flap reinforcement; (4) reconstruction of the pelvic floor, and (5) procedures such as sacrocolposuspension and urethral sling. (Docket no. 66, ex. A at 00294).

Next, Defendant seeks clarification with respect to the Court's order on Plaintiffs' Second Request for Production no. 4. Second Request for Production No. 4 asks Defendant to produce all records from the FDA relating to adverse event reports involving Permacol products. At the hearing, Plaintiffs stated that they are seeking documents pertaining to the lot or batch used in Mr. Avendt's surgery. (Docket no. 53 at 1612). Plaintiffs also argued that Defendant produced documents but redacted from those documents the lot numbers and serial numbers which prevents them from confirming that the devices are from the same batch or lot as was implanted into Mr. Avendt. Defendant argued that it produced all responsive documents and stated that there have been no other Medical Device Reports (MDR's) or reportable complaints for the lot of Permacol used in Mr. Avendt's surgery. The Court then directed Defendant to make that declaration in a written supplemental response to Plaintiffs.

In the instant motion Defendant seeks clarification that the Court's order limits Plaintiffs' request to Permacol devices for abdominal wall hernia repair from the same lot as Mr. Avendt's device, that being lot number 08B0901. Plaintiffs argue that Defendant produced MDR's based on Permacol devices originating from different batches than Mr. Avendt's device but based on incidents similar to Plaintiffs. They argue that two MDRs from incidents that occurred in the two months preceding Plaintiff's Permacol surgery and that occurred in the same general geographical region are of particular interest to them. Consequently, Plaintiffs argue that the Court should not limit request no. 4 as proposed by Defendant.

Plaintiffs' Second Request for Production no. 4 was narrowed during the motion hearing with input from the parties. Plaintiffs agreed on the record to limit the request to only those documents pertaining to the lot or batch used in Mr. Avendt's surgery. (Docket no. 53 at 1612).

Defendant has identified that as lot number 08B0901. The Court will not expand that request now.

The Court will grant Defendant's request for an extension of time to serve supplemental responses to Plaintiffs' First Interrogatory no. 16 and Second Request for Production no. 4.

IT IS THEREFORE ORDERED that Defendant's motion for clarification and for extension is **GRANTED**. On or before January 10, 2014 Defendant must do the following:

1. serve a supplemental written response identifying information responsive to First Interrogatory no. 16 as it relates to written correspondences dated 2003 through the present that were exchanged between Defendant and the FDA related to (1) the failure to test, prior to the date of Mr. Avendt's December 2008 ventral incisional hernia surgery, Permacol's application for use in abdominal wall hernia repairs, and (2) the failure to conduct testing on the clinical effects of the cross-linking process used in the manufacturing of Permacol. Request no. 16 is limited to testing conducted on Permacol as cleared in 510(k) K992556 and pertains only to the use of Permacol in abdominal wall hernia repairs.

2. produce all records from the FDA relating to adverse event reports involving Permacol products used for abdominal wall hernia repair and which were from lot number 08B0901 as discussed in this Order, or serve a supplemental written response on Plaintiffs containing a sworn declaration that after reasonable inquiry Defendant has produced all documents within its possession, custody, or control that are responsive to Second Request for Production no. 4.

IT IS FURTHER ORDERED that Defendant's motion is denied in all other respects.

NOTICE TO THE PARTIES

Pursuant to Fed. R. Civ. P. 72(a), the parties have a period of fourteen days from the date of this Order within which to file any written appeal to the District Judge as may be permissible under 28 U.S.C. 636(b)(1).

Dated: December 10, 2013

s/ Mona K. Majzoub
MONA K. MAJZOUB
UNITED STATES MAGISTRATE JUDGE

PROOF OF SERVICE

I hereby certify that a copy of this Order was served upon Counsel of Record on this date.

Dated: December 10, 2013

s/ Lisa C. Bartlett
Case Manager